

JUL 1 - 2005

K051184



19111 - 61<sup>st</sup> Avenue NE, Suite 5. Arlington, Washington 98223  
Office: 425-743-7343 Fax: 425-743-8795 Toll Free: 800-446-1666

### 510(k) Summary

#### Submitter Information:

United Contact Lens Inc.  
19111 61<sup>st</sup> Ave. NE #5  
Arlington, WA 98223  
Registration No. 2918644

Contact Person: Garold L. Edwards, O.D., F.A.A.O.  
Regulatory Consultant  
Telephone: (408) 221 - 3860  
Fax: (425) 743 - 8795

Date Prepared: May 4, 2005

#### Device Name:

Common Name: Soft (Hydrophilic) Contact Lens  
Trade/Proprietary Names: 55 SV (ocufilcon C) Soft  
(Hydrophilic) Contact Lens for Daily Wear  
  
55 Multifocal (ocufilcon C) Soft (Hydrophilic)  
Contact Lens for Daily Wear  
  
55 Toric (ocufilcon C) Soft (Hydrophilic)  
Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens  
Device Classification: Class II (21 CFR 886.5925)

#### Predicate Devices:

The 55 F (ocufilcon C) Soft (Hydrophilic) Single Vision Contact Lens, the 55 Multifocal (ocufilcon C) Soft (Hydrophilic) Contact Lens and the 55 Toric Contact Lens were selected as the predicate devices manufactured in the same facility, using the same formulation, under the same quality system packaging and sterilization processes as the subject devices.

**Description of Devices:**

The 55 SV, 55 Multifocal, and the 55 Toric (ocufilcon C) Soft (Hydrophilic) Daily Wear Contact Lenses are hemispherical flexible shells which cover the cornea and a portion of the adjacent sclera. The 55 Contact Lens is available in a single vision lens design, the 55 Toric Contact Lens is available in a double slab-off back surface design and the 55 Multifocal Contact Lens is available in an aspheric lens design. The lens material (ocufilcon C) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). Lenses are tinted using the color additive Reactive Blue 19.

**Comparison to Predicate Device**

<b>PARAMETER</b>	<b>55 SV, 55 Toric and 55 Multifocal Soft (hydrophilic) Contact Lenses for Daily Wear N/A</b>	<b>55 F, Toric 55 and Multifocal (ocufilcon C) Soft (hydrophilic) Contact Lenses for Daily Wear P920008/K941607</b>
<b>Submission number</b>		
<b>Material</b>	ocufilcon C	ocufilcon C
<b>Material classification</b>	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4
<b>Indication for use</b>	myopia, hyperopia, astigmatism and presbyopia	myopia, hyperopia, astigmatism and presbyopia
<b>Water content</b>	54.9%	54.4%
<b>Visible light transmittance</b>	98.9%	98.3%
<b>Dk (35° C)</b>	$18.77 \times 10^{-11}$	$18.78 \times 10^{-11}$
<b>Powers</b>	+12.00 D to -20.00 D; Continuous add power to +3.00 (55 Multifocal only); Cylinder powers -0.50 D to -2.50 D (55 Toric only)	+20.00D to -20.00 D Continuous add power to +3.00 (55 Multifocal only); Cylinder powers : -0.50 D to -6.00D (Toric 55 only)
<b>Color</b>	Blue visibility, Reactive Blue #19	clear
<b>Refractive index</b>	1.415	1.414
<b>Method of manufacture</b>	Molded	Lathed

**Indications for Use:**

The **55 SV (ocufilcon C) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **55 Multifocal (ocufilcon C) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The **55 Toric (ocufilcon C) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non- diseased eyes.

The lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems. Eye care practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical or hydrogen peroxide disinfecting systems.

**Description of Safety and Substantial Equivalence:**

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of the 55 SV, the 55 Multifocal, and the 55 Toric (ocufilcon C) Soft (Hydrophilic) Contact Lenses for Daily Wear, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. The 55 SV lenses were extracted and evaluated for presence of residue. Results showed no evidence of unsafe amounts of residue in the extracts. Physicochemical testing of the 55 lenses demonstrated equivalency to the predicate devices.

**Conclusion:**

Information submitted in the 510(k) establishes that the 55 SV, the 55 Multifocal and the 55 Toric Contact Lenses (ocufilcon C) have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that the physical lens properties are stable. Therefore, the devices are substantially equivalent to the predicate devices.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

United Contact Lens, Inc.  
c/o Garold L. Edwards, O.D., F.A.A.O  
Regulatory Consultant  
2091 Upper Scenic Drive  
Felton, CA 95018

Re: K051184

Trade/Device Name:

55 SV (ocufilcon C) Soft (hydrophilic) Contact Lens for Daily Wear  
55 Multifocal (ocufilcon C) Soft (hydrophilic) Contact Lens for Daily Wear  
55 Toric (ocufilcon C) Soft (hydrophilic) Contact Lens for Daily Wear

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL

Dated: May 4, 2005

Received: May 9, 2005

Dear Mr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

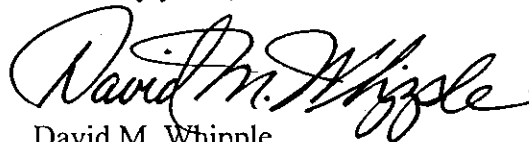
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, reading "David M. Whipple". The signature is fluid and cursive, with the first name "David" being the most prominent.

David M. Whipple  
Acting Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS STATEMENT

### Device Names:

55 SV (ocufilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

55 Multifocal (ocufilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

55 Toric (ocufilcon C) Soft (Hydrophilic) Contact Lens for Daily Wear

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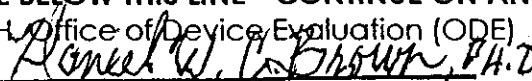
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Prescription Use  ☒ OR Over-the-Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K051184

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